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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/426,011      | 10/25/1999  | MICHAEL SIMONS       | BIS-043/CIP         | 1306             |

7590

04/07/2003

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EXAMINER

TELLER, ROY R

ART UNIT

PAPER NUMBER

1654

DATE MAILED: 04/07/2003

25

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/426,011

Applicant(s)

SIMONS ET AL.

Examiner

Roy Teller

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 29 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-14 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other:

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### **DETAILED ACTION**

The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1654

Applicant responded to a first office action with Paper No: 11, received 6/20/01, in which applicant amended claims 1-2, 5-6, and 9-11.

Claims 1-14 will be the subject of this office action.

### ***Election/Restrictions***

Upon further consideration, all outstanding rejections under 35 USC 112, 2<sup>nd</sup> paragraph; 102(b); and 103(a) are withdrawn and restriction to one of the following is required under 35 USC 121:

- I. Claims 1 and 3-10, drawn to a method for stimulating angiogenesis, classified in class 530, subclass 300.
- II. Claims 2 and 3-10, drawn to a method of altering proteasome-mediated degradation of peptides in-situ, classified in class 530, subclass 300.

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III. Claims 11-14, drawn to a family of PR-39 derived oligopeptides, classified in class 530, subclass 300.

Select **one** SEQ ID NO from SEQ ID NO: 3, SEQ ID NO: 4, or SEQ ID NO:5.

This application also contains claims directed to the following patentably distinct species of the claimed invention:

Select **one** type of cell from the group: endothelial, myocytes and myoblasts, fibrocytes and fibroblasts, epithelial, osteocytes and osteoblasts, neuronal and glial, erythrocytes, leukocytes, or progenitor cells (specify which progenitor cells).

Select **one** tissue from the group: myocardium, skeletal muscle, smooth muscle, an artery, a vein, lung, brain, kidney, spleen, liver, gastrointestinal tissue, nerve tissue, limbs, or extremities.

Select **one** means of introduction from the group: catheter-based means, injection-based means, infusion-based means, localized intravascular means, liposome-based means, receptor-specific peptide means, or slow releasing means for peptide secretion in living cells and sequestered organisms.

Select **one** amino acid where X is any amino acid.

Select **one** SEQ ID NO from SEQ ID NO: 3, SEQ ID NO: 4, or SEQ ID NO:5.

Applicant is advised that this is a restriction and not an election of species. Amendment of the claims to delete non-elected subject matter is required prior to allowance.

The inventions are distinct, each from the other because of the following reasons:

The inventions of groups I, II, and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP 806.04, MPEP808.01). In the instant application, the different inventions have different effects. The invention of group I is a method for stimulating angiogenesis, while the invention of group II is a method of altering proteasome-mediated degradation of peptides in-situ. The invention of group III is a family of PR-39 derived oligopeptides. Consequently, the inventions are patentably distinct due to their different effects.

Upon election of an invention from groups I-III above, applicant must further elect a patentably distinct sequence. **This is not an election of species.** Polypeptide sequences are structurally distinct compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each polypeptide sequence is presumed to represent an independent and distinct invention, subject to restriction requirement pursuant to 35 UCS 121 and 37 CFR 1.141.

Should applicant traverse on the ground that the sequences are not patentably distinct, applicant should submit or identify such evidence now of record showing the sequences to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the prior invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

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Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirements be traversed. See 37 CFR 1.143.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy Teller whose telephone number is (703) 305-4243. The examiner can normally be reached on Monday-Friday from 5:30 am to 2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (703) 306-3220. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

RT  
1654  
3/28/03

RT

*Brenda Brumback*  
**BRENDA BRUMBACK**  
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